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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,800	11/13/2006	Dieter Reif	50187	5864

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EXAMINER	
BERRIOS, JENNIFER A	

ART UNIT	PAPER NUMBER
1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,800	REIF ET AL.	
	Examiner	Art Unit	
	Jennifer A. Berrios	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *21-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the reply filed 7/27/2009.

Claims 21-32 have been withdrawn as being drawn to a non-elected group.

Claims 1-20 are currently pending examination.

Response to Arguments

1. Applicant's arguments, filed 7/27/2009, with respect to the rejection(s) of claim(s) 1-20 under 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites "a figure less than half..." It is unclear as to what is meant by "a figure less." Furthermore, the claim is unclear as to the limitations that are required.

4. Claim 16 recites the limitation "compact shaped body". There is insufficient antecedent basis for this limitation in the claim. It is unclear of the compact shaped

body is the bone formation agent of if the bone formation agent is simply a part of the compact body.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-2, 7, 12, 13-15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29922585 and Beam (WO 02/083194).

Regarding claim 1-2: DE '585 teaches a bone defect filler, or a bone formation afgent, with interconnecting micropores with an average size in the range of 0.5-10 µm (Pg 5). The sintered body has a total porosity of 60 vol%, micropores with an average size of 5 µm and macropores with an average size of 500 µm, but can range from 50-1000 µm (Pg 6 and 8). The macropores show a typical polyhedral shape over the entire size range (Pg 6). However it would have been obvious to one of ordinary skill in the art at the time of the invention to determine to appropriate shape required to achieve a desired set of results.

See MPEP 2144.04(B). B. Changes in Shape
In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.)
Tronzo v. Biomet, 156 F.3d at 1158-59, 47 USPQ2d at 1833 (Fed. Cir. 1998) (claims to generic cup shape were not entitled to filing date of parent application which disclosed "conical cup" in view of the disclosure of the parent application stating the advantages and importance of the conical shape.

With regard to the statistical distribution of the pores, it would have been obious to one of skill in the art to distribute the pores as necessary to achieve the best result through routine experimentation. B-tricalcium phosphate is used as the bone defect filler and is preferably employed as a polyhedral granulate in granulated sizes between

0.1-10 mm. Although this is slightly above the required particle size range, it's obvious to one of ordinary skill in the art to alter and optimize the sizes of the particles in order to achieve a desired set of results (Pg 6).

MPEP 2144.05 II: "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.)"

The pure phase B-tricalcium phosphate has an average particle size d50 < 10, thereby satisfying the limitation of a d50 values in the range of 5-20 µm.

Regarding claim 7: The bone defect filler is in the form of a polyherdral granulate in graduated sized between 0.1-10mm (claim 3).

Regarding claims 13 and 19: The bone defect filler as a molded sintered body, preferably has the shape of a cylinder, cuboid or a cube, all defined geometric designs.

Regarding claim 17: The bone defect fillers can be treated, as such it would be present on it's surface and/or pores, with an active agent , preferably antibiotics and/or growth factors suitable for bone defect healing (claim 6).

Regarding claims 18 and 20: These claims recite intended use and therefore have no patentable weight. As the limitations of claim 13 is taught above, the limitations of these claims jave been satisfied. Furthermore DE '585 teaches that the bone defect

filler can be machined into the form of an implant individually matched to a patient (claim 5).

DE '585 fails to teach the bone defect filler to comprise an isotropic structure.

Beam teaches a biostructure for implantation, having bimodal pore sizes (pg 120 and claims 3 and 9), made out of tricalcium phosphate (pg 135 and claim 111), which can be treated with substances such as antibiotics, growth promoting substance, etc (Pg 134, claim 103). Furthermore Beam refers to a structure which can be isotropic (pg 10).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the teaching of DE '585 and Beam. Because both DE '585 and Beam teach biostructure for implantation it would have been obvious to one of skill in the art to substitute one method for the other to achieve the predictable results of creating a biostructure comprising a isotropic structure.

Regarding claims 14-15: Any pore with any kind of depth is inherently in the shape of a tube, furthermore the pores of DE '585 satisfy the diameter range of 0.5-2mm. With regards to the statistical and tubular porosity, DE '585 teaches that total porosity lies between 60-80 vol% (Pg 6).

12. Claims 3-4 and 11-12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29922585 and Beam (WO 02/083194) as applied to claims 1-2, 7, 12, 13-15 and 17-20 above, and further in view of WO 92/21302.

DE '585 and WO '194 teach all the limitations of claim 1, but fail to teach the limitations further recited by claims 3-4, 11-12 and 16.

WO 92/21302 teaches an implant made of a porous, non-toxic material with a total porosity larger than 5% but not greater than 80% by volume. The implant is characterized in that it has three distinct pore sizes: .1-10 µm occupy 10-80% by volume; 10-50 µm occupy not more than 5% and 50-500 µm occupy from 5-40%.

It would have been prima obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of DE '585 / WO 02/083194 and WO 92/21302. One would be motivated to do so because by having a distribution of pore sizes, in this case three, one can combine a high strength and a capacity to meet high requirements as to a favorable situation for bone ingrowth as well as tissue ingrowth with an integrated interaction between soft and hard tissues (WO 92/21302, pg 2, lines 22-26). Finally one of skill in the art would expect to be successful because both references teach porous biostructures, which comprise calcium phosphate, for implantation that comprise a plurality of pore size distributions.

Regarding claim 11: Claim 11 disclosed matching the pore size distribution II and II to the granulate size. It would have been obvious to one of ordinary skill in the art to optimize the maxima of the pore size distributions in order to achieve improved results, through routine experimentation

Regarding claims 12 and 16" As demonstrated in the 112 2nd Paragraph above these claims are unclear as to what the limitations are. As such, since these limitations seem to describe properties of the bone formation agent of claim 3, it is expected that

the bone defect filler taught by DE '585 / WO '194 and WO '302, have the characteristics taught by the instant claims.

13. Claims 5, 8-10 and 18-20 rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29922585 and Beam (WO 02/083194) and WO 92/21302 as applied to claims 3-4 and 11-12 above, and further in view of US 6,521,246.

DE '585 / WO 02/083194 / WO/ 9221302 while teaching the bone formation agent, fails to teach the characteristics of the granulates of the bone formation agent.

The '246 patent teaches inorganic shaped bodies useful for bone grafting materials, cell growth scaffolds, drug delivery and more. It also teaches the methods of producing said inorganic bodies (column 1, lines 24-28). The '246 patent also teaches that these inorganic bodies can be formed into virtually any geometric shape (column 4, lines 2-3), although a uniform one is preferable, as suggested by the '246 patent claims 1, 14 and 22. The '246 patents goes on to teach that the uniform shaped body comprising meso-, micro-, and macroporous calcium phosphate, which comprises beta-tricalcium phosphate, is in the shape of a tube, block or sphere. The '246 fails to explicitly state the amount of beta-tricalcium phosphate present in the inorganic material, but one of skill in the art would understand that a substantial amount necessary to perform the functions (bone grafting, cell growth, etc) were present.

It would have been *prima face* obvious to one of ordinary skill in the art to combine the teachings of the '246 patent with teaching of DE '585 / WO 02/83194 / WO 92/21302. One of skill in the art would be motivated to do so as the embodiments of the

'246 patent (beta-tricalcium and the geometric shapes of the inorganic body) provide a large varieties of shaped bodies that can find wide used in surgery, laboratory and industrial processes and one of skill in the art would know that it's obvious to modify the shape of the biostructure in order to meet the desired needs (abstract of the '246 patent). Finally, one of ordinary skill in the art would be motivated to combine the above teaches, because all teach biostructures with a distribution of pore sizes (2-3) and the biostructure comprising tricalcium phosphate, for the use of bone grafting, tissue growth, and more.

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29922585 and Beam (WO 02/083194), WO 92/21302, and US 6,521,246 as applied to claims 5, 8-10 and 18-20 above, and further in view of Trisi et al (J Periodontics Restorative Dent 2003: 23:69-77), previously provided to applicant.

De '585 / WO 02/083194 / WO '302 and US '246 fails to teach the limitation of claim 6.

Trisi *et al* teaches the effect of pure phase beta-tricalcium phosphate in bone regeneration. It teaches that pure phase beta-tricalcium phosphate is characterized by a ≥ 99 purity of the beta isomer. This material is more rapidly and predictably resorbed and replaced by newly formed bone without any residue (pg 70, paragraph 4).

It would have been *prima face* obvious to one of ordinary skill in the art to combine the teachings of Trisi *ei al* and WO 02/083194. One of skill in the art would have been motivated to do so because by using pure phase beta-tricalcium phosphate

in the bone formation agent, the agent would be more rapidly resorbed and replaced by newly formed bone, therefore enhancing the function of the bone formation agent. Finally one of skill would expect to be successful because both teach agents used for bone formation and regeneration that comprise mainly calcium phosphate.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 270-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JB

/SUE LIU/

Primary Examiner, Art Unit 1639